



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

d16926

HL-35

60 8th Street, N.E.
Atlanta, Georgia 30309

November 21, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Norbert D. Thompson,
President
Technical Products Inc. of Georgia, USA
2416 Park Central Boulevard
Decatur, Georgia 30035

WARNING LETTER

Dear Mr. Thompson:

During a September 10-16, 1996 inspection of your firm, our investigator found that you are manufacturing and distributing a variety of silicone products. The SIL-TEC Elastomer, Siltec Malecot Catheter, Medical Grade Tubing (TPI 602-175), and Silicone Rods (TRI 515-01) are medical devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that the SIL-TEC Elastomer Medical Grade Sheeting, the Silicone Elastomer Medical Grade Tubing, and the Clear Rod devices are adulterated under Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) and do not have approved applications for premarket approval (PMA) in effect pursuant to Section 515(a) or approved applications for investigational device exemptions (IDE) under Section 520(g).

In addition, the SIL-TEC Elastomer Medical Grade Sheeting, the Silicone Elastomer Medical Grade Tubing, and the Clear Rod devices are misbranded under Section 502(o) of the Act in that notices or other information respecting the devices were not provided to the FDA as required by Section 510(k). The continued distribution of these devices is a serious violation of the Act.

Investigator Hilscher also documented several significant deviations from the Good Manufacturing Practice for Medical Devices (GMPs) as set forth in Title 21, Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to maintain device history records to demonstrate that devices are manufactured in accordance with the device master record. The device history record must include the dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used.

You have failed to establish a formalized review of finished devices to ensure that device specifications have been met. Prior to release for distribution, each production run, lot or batch shall be checked and, where necessary, tested for conformance with device specifications. No documentation was available to indicate any review by quality control or quality assurance personnel prior to final release of the devices.

You have failed to maintain any records of acceptance and rejection of incoming components. A designated individual should accept or reject all incoming components in accordance with written procedures.

You have failed to implement planned and periodic audits of the quality assurance program. These audits are to verify compliance with the quality assurance program. The audits should be performed in accordance with written procedures by an appropriately trained individual. No such internal audits have been conducted.

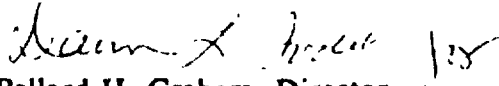
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with you. The specific violations noted in this letter and in the FDA 483 are symptomatic of serious underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submission of devices to which the GMP deficiencies are reasonably related will be cleared until these violations have been corrected. Also, no request for Certificates For Product for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,


Ballard H. Graham, Director
Atlanta District